K083460
Page 1 of 2

5. 510(k) Summary

APPLICANT/ SUBMITTER:

B. Braun Avitum AG
Schwarzenberger Weg 73-79
Melsungen, GERMANY D-34212

FEB 18 2010

CONTACT:

Bonnie J. Kincaid, RAC
Manager, Regulatory Affairs
B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
Phone: 610-596-2970
Fax: 610-266-4962

DEVICE NAME: Dialog+® Hemodialysis System with Adimea™ Option

COMMON OR USUAL NAME: High permeability hemodialysis system

DEVICE CLASSIFICATION: Class II per 21 CFR §876.5860:
Product Code KDI

PREDICATE DEVICE(S): Dialog+® Hemodialysis System

DESCRIPTION: The Adimea option to the Dialog+® Hemodialysis System provides an alternate means of obtaining effectiveness information on the patient's hemodialysis treatment during a double-needle procedure by continuously measuring the UV absorption in the spent dialysate line. This optional feature includes controlling software, ancillary hardware (a double-beam spectrophotometer) and electronics to operate the Adimea function. Adimea software provides the Kt/V calculation, an on-line measure of dialysis treatment effectiveness.

INTENDED USE: This dialysis machine can be used for implementing and monitoring hemodialysis treatments for patients with acute or chronic kidney failure. The system can be used in hospital, health center and outpatient dialysis center settings when prescribed by a physician.

510(k) Summary (*continued*)

The following types of renal replacement therapy can be carried out with the Dialog+ System:

Hemodialysis (HD) with or without phases of pure ultrafiltration –

- High flux hemodialysis
- Low flux hemodialysis

SUBSTANTIAL EQUIVALENCE:

The Dialog+ System with Adimea Option has the same intended use and utilizes the same fundamental technology as the predicate Dialog+ System. The Dialog+ System with Adimea Option is also similar to the predicate device in design and materials. The optional design feature that incorporates a spectrophotometric method of measuring the UV absorption in the spent dialysate line and the software calculation of Kt/V does not have a significant affect upon the fundamental technology of the Dialog+ System, since it operates as a discreet component / function of the Dialog+ System. Software requirements specifications for Adimea have been met and verification and validation testing is complete. This testing demonstrates that there are no differences between the predicate and the proposed device that raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JUL - 8 2010

B. Braun Avitum AG
c/o Ms. Bonnie Kincaid, RAC
Manager, Regulatory Affairs
B. Braun Medical, Inc.
901 Marcon Boulevard
ALLENTOWN PA 18109-9341

Re: K083460
Trade/Device Name: Dialog+® Hemodialysis System with Adimea Option
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: February 5, 2010
Received: February 12, 2010

Dear Ms. Kincaid:

This letter corrects our substantially equivalent letter of February 18, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

4. Indications for Use

510(k) Number (if known): K083460

Device Name: Dialog+® Hemodialysis System with Adimea Option

Indications for Use:

This dialysis machine can be used for implementing and monitoring hemodialysis treatments for patients with acute or chronic kidney failure. The system can be used in hospital, health center and outpatient dialysis center settings when prescribed by a physician.

The following types of renal replacement therapy can be carried out with the Dialog+ System:

Hemodialysis (HD) with or without phases of pure ultrafiltration –

- High flux hemodialysis
- Low flux hemodialysis

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083460